

AMENDMENT TO THE CLAIMS

This listing of claims will replace all prior versions of claims in the application:

Listing of Claims:

Sub
Exam

1. (Currently Amended) A biologically pure culture of a single-celled organism, Spiky Rotating Cells (SPR), wherein said organism causes a disease in humans and comprises the following biological characteristics has: (i) provisional classification as a protozoan (ii) a spherical shape measuring approximately 7-8 μm as a solitary single-celled organism; (iii) ~~spiky membrane projections~~; (iv) a refractile cell membrane; (iv) multiple circumferential spiky projections of the cell membrane; (v) rotatory motility; (vi) periodic ~~colonial~~ clustering behavior to form colonies; and (vii) existence ~~exists~~ in an extracellular environment.

2-4 (Cancelled)

Sub
Exam

5. (Currently Amended) A method of diagnosing an SPR infection in a human patient, said method comprising the steps of:

a) obtaining a sample from said patient; and

b) testing said sample for the presence of an organism that causes a disease in humans, said organism having the following biological characteristics: (i) provisional classification as a protozoan (ii) a spherical shape measuring approximately 7-8 μm as a solitary single-celled organism; (iii) ~~spiky membrane projections~~; (iv) a refractile cell membrane; (iv) multiple circumferential spiky projections of the cell membrane; (v) rotatory motility; (vi) periodic ~~colonial~~

clustering behavior to form colonies; and (vii) existence ~~exists~~ in an extracellular environment;
wherein the presence of said organism indicates an SPR infection.

~~6~~ (Previously Presented) The method of claim 5, wherein said method further comprises, after step a), testing the pH of said sample, wherein a pH greater than 6.0 is further indicative of the presence of said SPR infection.

7. (Previously Presented) The method of claim 5, wherein said patient is a male, and wherein step a) comprises obtaining said sample from the urethra of said male patient, wherein said sample comprises a secretion found in the urethra of said male patient.

8. (Cancelled)

~~8~~
~~9~~ (Previously Presented) The method of claim 5, wherein step b) comprises admixing said sample with saline and examining said sample by microscopy, wherein said SPR infection is confirmed by the presence of an organism comprising said biological characteristics.

~~11~~
~~10~~ (Previously Presented) The method of claim 5, wherein said patient is a female, and wherein step a) comprises obtaining a sample from the vagina of said female patient, wherein said sample comprises a cervico vaginal secretion from said female patient.

11. (Cancelled)

12. (Previously Presented) The method of claim 5, wherein said patient has a skin eruption or lymph node abscess, and wherein the sample of step a) comprises a secretion from said skin eruption or abscess.

13. (Cancelled)

¹³~~14~~ (Previously Presented) An instrument for collecting a sample from a male patient, wherein said sample comprises urethral secretions, said instrument comprising:

- a) a handle portion; and
- b) attached to said handle portion, a means for collecting a secretion from the reproductive system of said male patient, wherein said collecting means is sized and shaped for insertion into the distal end of the urethra of said male patient and comprises a loop region with an opening, wherein said loop region is positioned at the end of said device opposite said handle portion; and
- c) a pH sensor positioned adjacent the collecting means, wherein said pH sensor comes into contact with said sample and detects the pH of said sample.

¹⁴~~15~~ (Currently Amended) An instrument for collecting a sample from a female patient, wherein said sample comprises cervico vaginal secretions, and detecting the presence of SPR in said secretions, said instrument comprising:

- a) a handle portion;
- b) attached to said handle portion, a means for collecting cervico vaginal secretions from said female patient, wherein said collecting means comprises a loop region with an opening, wherein said loop region is positioned at the end of said device opposite said handle portion; and

c) a pH sensor positioned adjacent the collecting means, wherein said pH sensor comes into contact with said sample and detects the pH of said sample.

16. (Cancelled)

17. (Currently Amended) A method of treating an SPR infection in a patient, said method comprising:

a) diagnosing said SPR infection, wherein the organism causing said SPR infection causes a disease in humans and comprises the following biological characteristics: (i) provisional classification as a protozoan (ii) a spherical shape measuring approximately 7-8 μm as a solitary single-celled organism; (iii) ~~spiky membrane projections~~; (iv) a refractile cell membrane; (iv) multiple circumferential spiky projections of the cell membrane; (v) rotatory motility; (vi) ~~periodic colonial clustering behavior to form colonies~~; and (vii) existence ~~exists~~ in an extracellular environment; and

b) upon obtaining a positive diagnosis in step a), administering to said patient an SPR-inhibiting amount of an anti-SPR agent selected from the group consisting of itraconazole, ofloxacin, and metronidazole.

18. (Cancelled)

2 ~~19~~. (Previously Presented) The culture of claim 1, wherein said extracellular environment is skin, fluid of the genital tract, or the extracellular fluid of other organs.

³~~20~~. (Previously Presented) The culture of claim 1, wherein said disease is nongonococcal urethritis.

⁴~~21~~. (Previously Presented) The culture of claim 1, wherein said organism proliferates in Diamond's media.

22-34 (Cancelled)

¹⁶~~35~~. (Previously Presented) A single-celled organism having accession number ATCC PTA-2129.

⁹~~36~~. (Previously Presented) The method of claim ⁸~~9~~, wherein said extracellular environment is skin, fluid of the genital tract, or the extracellular fluid of an organ.

¹⁰~~37~~. (Previously Presented) The method of claim ⁸~~9~~, wherein said organism proliferates in Diamond's media.